LEGISLATIVE AND REGULATORY UPDATE

September 2004

AAMC Legislative and Regulatory Update
September 2004

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**"So they [the Parliament] go on in strange paradox,
decided only to be undecided, resolved to be irresolute,
adamant for drift, solid for fluidity, all-powerful to be impotent."**

Winston Churchill

Introduction

September in Washington used to signal the start of a frenetic rush by the Congress to complete its work before it could adjourn for the year. In most years, much of the attention would focus on the 13 appropriations bills that are supposed to be, but often are not, enacted before the October 1 start of the federal fiscal year. However, Congress abandoned this routine two years ago when conservatives and moderates reached an impasse over the funding levels in several appropriations bills. Neither the conservatives, eager to show fiscal restraint, nor the moderates, seeking additional funds for priorities such as education and health, wanted to face the voters in that year's election having given ground to the other side. So the heavy political lifting was put off until after the election, when the appropriations process continued to sputter and stall, not producing a final accord on the spending bills until well into February. Last year, even without electoral expectations, the appropriations process again lumbered into the new year before reaching its conclusion.

Earlier this year, in the face of renewed calls for fiscal discipline that produced a congressional budget blueprint calling for a freeze of most domestic spending, Congressman Bill Young (R-Fla.) and Senator Ted Stevens (R-Alaska), chairs of the House and Senate Appropriations Committees, respectively, predicted it would be impossible to pass more than the defense, and possibly homeland security, appropriations bills prior to the election. This prophecy is well on its way to being fulfilled. To date, only the defense appropriation has been signed into law. Of the remaining 12 spending bills, the House has passed 9, but the Senate has passed none, and only 3 bills have been reported out by the Senate Appropriations Committee. With the twin distractions of the election and the 9/11 commission report, significant progress on appropriations or any other legislation in the coming month is doubtful. The likely result will be a series of continuing resolutions (CRs) to keep the government operating after October 1 until the appropriations bills are completed.

What follows is a summary of the major legislative and regulatory actions of importance to medical schools and teaching hospitals as of August 31, 2004. Listed at the end of each item is the last name of the AAMC staff person who is responsible for monitoring that issue. If you wish to receive additional information on a specific issue, you are encouraged to visit the AAMC Government Affairs and Advocacy Web site at: **www.aamc.org/advocacy/start.htm** or to contact these individuals directly.

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Overview of FY 2005 Appropriations

While the House has made progress toward completing the FY 2005 appropriations bills – approving 10 of the 13 bills prior to the August recess – Senate action on the bills has been slowed by the Senate's inability to approve the conference agreement on the FY 2005 budget resolution (S Con Res 95 – H Rept. 108-498). Without the budget resolution's spending cap in place, Republicans could not use procedural grounds to prevent Democratic amendments to add money to the bills. GOP leaders finally attached an $821.4 billion discretionary spending cap to the defense appropriations conference bill, which the President signed on August 5 (PL 108-287). This sets the stage for Senate action when Congress returns to Washington after Labor Day by allowing Senate Appropriations Chairman Ted Stevens (R-Alaska) to set spending allocations for each of the appropriations subcommittees and enforce these limits with budget points of order when the spending bills come to the Senate floor.

Just exactly what action the Senate will take has been the subject of some speculation during August. Republican leaders reportedly are considering using the homeland security spending bill – legislation that many observers believe Congress must pass prior to adjourning in early October – as a vehicle for an omnibus appropriations package that would combine most or perhaps all of the unfinished spending bills. That strategy would force Democrats to choose between supporting the package or being seen as delaying passage of needed homeland security funds.

Another question is the fate of the three bills considered by many to be the most contentious: Labor-HHS-Education, VA-HUD-Independent Agencies, and Transportation. Although the House Appropriations Committee has cleared all three measures, prospects are mixed for House passage in time to be included in an omnibus spending bill approved before the election. ***[Moore, Fishburn]***

FY 2005 Labor-HHS-Education Appropriation

The House Appropriations Committee approved its FY 2005 Labor-HHS-Education appropriations bill on July 14. The committee adopted the recommendations approved by the Labor-HHS-Education Subcommittee on July 8. However, the committee did not file the report on the bill prior to the August recess.

On April 29, the AAMC submitted a statement for the record to the House Labor-HHS-Education Appropriations Subcommittee on FY 2005 funding for the Department of Health and Human Services. The Association's statement outlined its funding recommendations for the National Institutes of Health, the Title VII and VIII health professions education programs, the Agency for Healthcare Research and Quality, the National Health Service Corps, and the Council on Graduate Medical Education. The AAMC's statement is available at: **www.aamc.org/advocacy/library/laborhhs/testimony/2004/042904.pdf**. ***[Moore, Fishburn]***

National Institutes of Health: The House bill provides $28.4 billion, an increase of $782 million (2.8 percent) over FY 2004, and the same level proposed by the Administration. All

institutes and centers are funded at the Administration-proposed levels. The bill also retains the salary cap for extramural grants at Executive Level I ($175,700 in 2004).

The House bill allots $1.09 billion to the National Center for Research Resources (NCRR), a 7.2 percent cut caused, in part, by the elimination of funding for extramural facilities construction. The bill provides $150 million through the National Institute for Allergy and Infectious Diseases to fund the construction of an additional 20 BSL-3 laboratories for biodefense research. ***[Moore, Fishburn]***

Title VII and VIII Health Professions: While restoring much of the funding eliminated in the president's proposed budget, the bill contains an 8.4 percent cut below the FY 2004 level for the Title VII health professions education programs. The bill funds most of the Title VII programs at the FY 2004 level except for primary care medicine and dentistry (cut 21.9 percent), rural training (cut 63 percent), workforce information and analysis (eliminated), and public health, preventive medicine and dental public health programs (cut 24 percent). Title VIII nursing programs receive a 3.5 percent increase. Advanced nursing education receives an 8.5 percent cut below FY 2004, while the nurse education, practice and retention program, and the loan repayment and scholarship program see increases of 15.8 and 18.7 percent, respectively. ***[Froyd]***

National Health Service Corps: The House bill provides level funding of $169.9 million for the Corps, $35 million less than the president's budget. ***[Fishburn]***

Other HRSA Programs: The Children's Hospital Graduate Medical Education is allocated $303.3 million in the House bill, the same level recommended in the Administration's budget and an $88,000 increase over FY 2004. ***[Froyd]***

Agency for Healthcare Research and Quality (AHRQ): The bill provides $303.7 million, the same level as last year and proposed in the president's budget. All money is derived from transfers from other Public Health Service programs. ***[Froyd]***

Bioterrorism Preparedness: The House bill funds the bioterrorism hospital preparedness program administered by the Health Resources and Services Administration (HRSA) at the FY 2004 level of $542.6 million, while the funding for the Centers for Disease Control and Prevention (CDC) state bioterrorism program is boosted $130.5 million to $1.637 billion, an 8.6 percent increase. The House bill adopts the Administration's proposal for an additional $47 million for NIH to support research on nuclear and radiological medical countermeasures. ***[Froyd]***

Centers for Disease Control and Prevention: The House bill cuts the CDC budget by 2.2 percent to $4.48 billion. ***[Fishburn]***

FY 2005 VA-HUD Appropriations

The House Appropriations Committee July 22 approved its version of the FY 2005 VA-HUD and Independent Agencies Appropriations bill. The full Committee adopted the funding recommendations approved by the VA-HUD subcommittee on July 20. Similar to the Labor-HHS-Education bill, the committee did not file a report prior to the August recess. ***[Fishburn]***

VA Medical and Prosthetics Research: The House bill includes a recommendation of $385 million for the VA research program, a decrease of $20.6 million (5.1 percent) from FY 2004. ***[Fishburn]***

VA Medical Care: The House bill includes a total of $30.3 billion for the Veterans Health Administration (VHA). This includes $19.5 billion for Medical Services, $4.7 billion for Medical Administration, and $3.7 billion for Medical Facilities. The total appropriation is $1.9 billion (6.7 percent) more than FY 2004. ***[Fishburn]***

National Science Foundation: The House bill includes a recommendation of $5.5 billion for the National Science Foundation (NSF), a decrease of $111 million (2.1 percent) from the previous year. The total includes $4.2 billion for NSF Research, a decrease of approximately $50 million (1.0 percent). ***[Fishburn]***

VA Physician Pay Bill

The Senate Veterans Affairs Committee July 20 approved by voice vote S. 2484 as amended, the "Department of Veterans Affairs Health Care Personnel Enhancement Act of 2004," also known as the VA physician pay bill. The substitute bill will create three new pay elements, one for base/longevity pay, one for market pay, and one for incentive pay.

Under the amended proposal, the base pay system includes 15 tiers ranging from $90K at Tier 1 to $133K at Tier 15, with about a 2.5 percent increase between tiers. VA physicians would start at Tier 1 and automatically be moved up to the next tier every 2 years. The base salaries would increase with the overall federal pay increases that occur approximately annually. The market pay system would allow for the Secretary to set maximum and minimum salaries for VA physicians nationwide, with maximum and minimum parameters by specialty and subspecialty, and multiple tiers within each specialty or subspecialty. An individual VA physician's total salary would be within the set parameters but specifically determined by the local facility on the recommendation of the Professional Standards Boards (PSBs). The parameters of the market pay system would be adjusted at least every two years by the Secretary, who would be required to consult two appropriate national pay surveys before making his recommendation. The third element of the proposed system would be incentive pay, and would include the ability for a physician to receive an annual bonus of up to $10,000. There would be no salary reductions. The amended language does not include language from the original bill that would prohibit VA Chiefs of Staff or other officers of the affiliated institution from receiving compensation from the affiliate.

After agreeing to the basic principles in the amended Senate bill, Senate and House staff have been negotiating further changes to the legislation throughout the month of August. As a result of the negotiations, the provisions related to incentive pay have been eliminated, because they were opposed in principle by House Democrats and Republicans. Additionally, the pay scales announced by the Secretary every two years would be published in the Federal Register and subject to public comment before being implemented.

At this point, there are two procedural options available to the Senate Committee: substitute the new compromise language for the language reported out of committee and seek Senate passage of the new compromise bill before sending it on to the House; or seek passage of the bill as amended by the committee and let the House insert the compromise language that could then be sent back to the Senate for adoption or approved in a conference committee. As yet there is no indication of what course of action will be taken.

At an October 21, 2003, House Veterans Affairs Health Subcommittee hearing on the proposal, Tom Lawley, M.D., dean of the Emory School of Medicine and Chairman of the AAMC VA-Deans Liaison Committee, testified on behalf of the AAMC in support of reforming the VA physician pay system. A copy of Dr. Lawley's testimony is available on the Web at: **www.aamc.org/advocacy/library/vahud/testimony/2003/102103.pdf**. ***[Fishburn]***

Higher Education Reauthorization

Republicans on the House Committee on Education and the Workforce introduced legislation on May 5 to reauthorize the Higher Education Act until 2011. The "College Access and Opportunity Act of 2004" (H.R. 4283) intends to expand access to higher education for low and middle income students by "strengthening Pell Grants, student aid, student access" and "reducing loan costs, fees and red tape for students and graduates." Committee Leadership indicated in late June that the legislation would not be considered by the Committee this year, but will serve as the basis for a renewed effort to reauthorize the Higher Education Act in the Spring of 2005.

The legislation includes several student aid provisions of interest to medical students and residents.

Specifically, the legislation calls for annual loan limits for unsubsidized Stafford loans to be increased from the current $10,000 to $12,000. The bill also calls for eliminating the scheduled change from a variable rate on Stafford loans to a fixed rate of 6.8 percent on July 1, 2006. Under the proposal, all loans, including consolidation loans, would be subject to a variable interest rate. The measure also would eliminate the "single-holder" rule that currently limits borrowers' ability to shop around for a consolidation loan. Additional provisions reduce origination fees from 3 percent to 1 percent and close a loophole that allows lenders to reap "windfall profits" by requiring lenders to return excess profits to the federal government.

On April 19, the AAMC along with 24 other physician groups sent a letter to the chairs and ranking members of the Senate Health, Education, Labor and Pensions Committee, and the House Committee on Education and the Workforce, the two committees of jurisdiction for the upcoming reauthorization of the Higher Education Act, calling on Congress to increase the annual Stafford subsidized loan limits and extend the Economic Hardship Deferment. Specifically, the physician group letter calls on Congress to increase subsidized Stafford loan limits for graduate and professional students from the current $8,500 to at least $12,000. Loan limits have not increased since 1992 and enacting such a change would "help medical students choose a specialty and practice location driven by their education, experiences, and aspirations, rather than by the amounts of their educational loan liabilities." The letter also calls for an extension of the Economic Hardship Deferment to the length of a required residency. The deferment is currently available for only three years, less than the length of many residencies. The letter also recommends that all school-certified education loans be included in the calculation for determining eligibility for the Economic Hardship Deferment. The letter is available on the AAMC Government Affairs and Advocacy Web site at: **www.aamc.org/advocacy/library/educ/corres/2004/041904.pdf**.

Additionally, the AAMC and 44 other higher education groups May 26 signed a letter organized by the American Council on Education (ACE) that offers the community's observations on H.R. 4283. The letter, addressed to House Education and the Workforce Committee Chairman John Boehner (R-Ohio) and Subcommittee on 21st Century Competitiveness Chairman Howard "Buck" McKeon (R-Calif.), applauds the legislators' efforts and notes many positive features of the bill including the reduction of origination fees and small increases in student loan limits. However, the letter also states that the bill will "alter the basic relationship between the federal government and institutions of higher education" and therefore the groups determined that they "cannot support" the bill in its current form. The letter includes 16 pages of comments and suggested changes to the legislation, focusing primarily on the increased regulatory and reporting burdens imposed by the bill and the impact on accreditation and transfer of credit policies. The letter supports continuing with a variable rate for Stafford loans, but recommends capping the rate at 6.8 percent, rather than the 8.25 percent proposed in the bill. Under current law, all Stafford loans will move to a fixed 6.8 percent on July 1, 2006. The letter does not make specific recommendations regarding interest rates for consolidation loans, but notes that some associations have proposed that the consolidation interest rate also be capped at 6.8 percent. The full text of the letter is available on the ACE Web site at: **www.acenet.edu/hena/pdf/2004_05_26_HR4283.pdf**. ***[Fishburn]***

Medicare Graduate Medical Education

In the FY 2005 Medicare Inpatient Final Rule, released in the August 11 *Federal Register* (69 FR 48916), the Centers for Medicare and Medicaid Services addressed three issues that had been advocated by the AAMC. The final rule, a summary and analysis of the final rule, and the Association's comment letter on the proposed rule are available at: **www.aamc.org/advocacy/library/teachhosp/hosp0054.htm**

Resident Limit Redistribution Program: The final rule implements section 422 of the "Medical Prescription Drug, Improvement, and Modernization Act of 2003" (MMA), entitled "Redistribution of Unused Resident Positions." The intent of this provision is to reduce the resident limits for those hospitals that are not fully "using" their caps and "redistribute" these slots to hospitals that demonstrate a need to have their caps increased. The resident limit reductions and increases are scheduled to go into effect on July 1, 2005.

The final rule establishes the process for determining whether, and by what amount, a hospital's resident cap will be reduced. It also specifies the application process for hospitals seeking increases to their resident caps and the criteria CMS will use to determine which hospitals will receive cap increases. The CMS criteria are particularly important in the event that the cap slot "demand" exceeds "supply."

Applications to receive additional cap slots are generally due December 1, 2004. ***[Fisher]***

Initial Residency Period (IRP): Certain specialties, such as radiology, anesthesiology, dermatology, neurology, psychiatry, ophthalmology, and physical medicine and rehabilitation, require that residents spend a year in general clinical training, with the remaining years comprising specialty-specific training. Under requirements established by Accreditation Council for Graduate Medical Education (ACGME), the organization that accredits allopathic residency programs, the general clinical year requirement can be met through one of two pathways: by 1) spending the first year in internal medicine, pediatrics, or surgery, or 2) participating in a one-year, freestanding "transitional year" program. Because CMS bases a hospital's DGME payment on the residency in which the resident meets the general clinical year requirement, CMS "counts" differently residents who participate in various types of first year general training programs.

Under the final rule, effective with cost reporting periods beginning on or after October 1, 2004, if a hospital can document that a resident simultaneously matched for one year of training in a particular specialty residency program and for a subsequent period of training in a different specialty program, the resident's IRP will be determined based on the period of board eligibility associated with the second program.

This is a significant clarification and the AAMC was pleased to see it in the final rule. However, the AAMC continues to believe that the best solution is that for residents whose first year of training is completed in a program that provides a general clinical year of training, an IRP should be assigned based on the specialty the resident enters in the second year of training. This is consistent with Congressional intent as contained in conference report language that accompanied the MMA.

Because such policy results in inequitable DGME payments to hospitals and is illogical, CMS' interpretation should be corrected. The FY 2005 inpatient final rule (or an interim final regulation) should reflect Congressional intent by clarifying that for a resident whose first year of training is completed in a program that provides a general clinical year as required by ACGME for certain specialties, an IRP should be assigned based on the specialty the resident enters in the second year of training. ***[Fisher]***

Volunteer Physicians: In the final rule, CMS did not adopt the AAMC's request to extend and expand the MMA's one-year moratorium related to volunteer physicians in family medicine programs. The final rule did appear to provide some flexibility regarding volunteerism when the supervising physician is a solo practitioner.

CMS also noted in the final rule that the MMA directed the Inspector General of the Department of Health and Human Services to conduct a study of the appropriateness of alternative methodologies for payment of residency training in non-hospital settings and to submit a report by December 8, 2004. CMS stated that it will review this report and may consider policy and regulatory changes at that time.

The AAMC is concerned that because the report will not be completed in time to permit Congressional review before the moratorium expires, Congress should also extend the moratorium by an additional two years so that Congress will have an appropriate amount of time to review the study and act upon its recommendations. The AAMC also strongly supports the expansion of the moratorium to all specialties based upon the fact that the IG report will evaluate all residency programs, not just family medicine residency programs. It is more than appropriate for the moratorium to provide protection for all residency programs. ***[Fisher, Davis Boyle]***

2005 Medicare Inpatient Prospective Payment System Final Rule

On August 11, the Centers for Medicare and Medicaid Services (CMS) published in the *Federal Register* (69 FR 48916) the final rule containing changes to the Medicare hospital inpatient prospective payment system (PPS) and the PPS payment update for Federal fiscal year (FFY) 2005. This rule finalizes changes and policies contained in the May 18 proposed rule (69 FR 28196). The AAMC submitted an extensive comment letter on the proposed rule. The final rule, a summary and analysis of the final rule, and the Association's comment letter are available at: **www.aamc.org/advocacy/library/teachhosp/hosp0054.htm**.

The final rule contains a number of significant provisions regarding Medicare policies for direct graduate medical education (DGME) and indirect medical education (IME) payments. Foremost among these are the regulations and instructions for implementation of the Medicare resident limit redistribution program, mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (see page 5). The final rule also addresses Medicare payments for residents training at nonhospital sites, DGME initial residency period determinations (the so-called "preliminary year" issue), the DGME per resident amount freeze, and the IME payment level.

Other policies and changes of interest to teaching hospitals include the update factor for the inpatient PPS base payment rate, outlier payments, counting beds for purposes of the IME formula, a change relating to the Medicare disproportionate share (DSH) payment methodology, changes to the metropolitan statistical area (MSA) definitions and computation of wage index values, and new services that will receive pass through payments.

The final rule contains a redesignation of the DGME regulations within volume 42 of the Code of Federal Regulations (CFR). Currently the regulations are contained in section 413.86. This section is being divided into nine sections, sections 413.75 through 413.83. ***[Fisher]***

Medicare Physician Fee Schedule

The Medicare Physician Fee Schedule proposed rule was published in late July. Section 601 of the ''Medicare Prescription Drug, Improvement and Modernization Act of 2003'' (MMA), (PL 108-173) sets the CYs 2004 and 2005 Medicare physician payment conversion factor (CF) update at "not less than 1.5%."

If the MMA update had not been in place, the CF update for 2004 would have been –4.5 percent. According to the proposed rule, the 2005 CF update is projected to have been –3.7 percent without the required legislative update of 1.5 percent. The cumulative nature of the current Sustainable Growth Rate (SGR) methodology for calculating updates absent legislative fixes is expected to result in negative CF updates of approximately 5 percent for 2006 – 2012. The SGR was established in the Balanced Budget Act (BBA) of 1997 and is designed to limit growth in Medicare spending on physician and other health care provider services. The physician payment formula is the only Medicare payment formula that sets a spending target rate.

The proposed rule also includes a 5 percent bonus for both primary care and specialty physicians working in underserved areas. Further, the rule provides coverage for a variety of new benefits. Included among these are a "Welcome to Medicare" physical, including an EKG and other diagnostic tests. Beneficiaries will be able to receive this benefit during their first six months of Medicare eligibility. Coverage will also be provided for heart disease and diabetes screenings.

The Medicare fee schedule has reimbursed providers for chemotherapy and other office-administered drugs. The Centers for Medicare and Medicaid Services (CMS) recognized that it was often reimbursing for those drugs above market prices and that physicians were using the reimbursement to help offset costs associated with storing, preparing and administering the drugs. In an effort to make payments more accurate, CMS was directed by Congress to revise the drug prices downward and to reimbursement for administration services. CMS is setting the reimbursement rates at the average sale price plus 6 percent. The American Medical Association (AMA) and specialty societies are developing new CPT codes for drug administration to ensure accurate reimbursement.

However, the AAMC and the physician community has long argued that expenditures on drugs should not be included in the SGR calculations, since they are not part of the physician fee schedule. Inclusion in the SGR can negatively impact the CF updates when expenditures on drugs increase. To that end, AAMC joined AMA and other physician groups on a July 16, 2004 letter sent to CMS Administrator Mark McClellan. The letter urged Dr. McClellan to implement CMS' authority to remove the cost of drugs and adequately account for new covered benefits resulting from law and regulation from the SGR. ***[Dodero, Davis Boyle]***

Medicare CY 2005 Outpatient PPS Proposed Rule

In the August 16, *Federal Register*, the Centers for Medicare and Medicaid Services (CMS) published its proposed rule updating the Medicare outpatient prospective payment system for calendar year 2005. According to the CMS analysis, Medicare rates for hospital outpatient services will increase 3.3 percent in 2005. The rule includes a proposal to pay hospitals for new drugs and biologicals as soon as the Food and Drug Administration approves them, rather than having them wait several months until a code and payment rate are assigned. CMS will accept comments on the proposed rule until October 8.

AAMC members who wish to submit written comment by the October 8 deadline (reference file code CMS-1427-P) should send them (an original and three copies), to:

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-1850

Comments also may be submitted electronically to:
http://www.cms.hhs.gov/regulations/ecomments (attachments should be in Microsoft Word, WordPerfect, or Excel; CMS prefers Microsoft Word). ***[Fisher]***

Medicaid Funding

Senators John Rockefeller (D-W.V.) and Gordon Smith (R-Ore.) July 15 introduced the "State Fiscal Relief Act of 2004" (S. 2671), which would temporarily extend the state fiscal relief provisions passed as part of the 2003 economic stimulus package that expired July 1.

The provisions in S. 2671 are retroactive to July 1, and grant states a temporary 1.26 percent increase in their Federal Medical Assistance Percentage (FMAP, or "match"). The 15-month increase would expire September 30, 2005, and cost $4.8 billion.
S. 2671 also includes up to $1.2 billion in "Transitional Funds" to help states implement federal mandates outlined in the Medicare Modernization Act (MMA) related to dual eligibles and low-income individuals who qualify for Medicare cost-sharing. States could apply the funds to MMA-related expenditures made from October 1, 2004, through April 1, 2006.

Acknowledging that the new bill is significantly less generous than the previous round of state fiscal relief, Senators Rockefeller and Smith consider the legislation a "workable phase-down transition" in federal assistance. ***[Mitchell]***

Medical Liability Reform Legislation

The AAMC has worked with Congressional leadership and other members of the physician community to help assure medical liability reform has a place on the legislative agenda during the next Congress.

Despite several attempts by Senators Judd Gregg (R-N.H.) and Bill Frist (R-Tenn.), the Senate could not secure the 60 votes necessary to avert a filibuster over medical liability reform legislation. On May 12, the House passed AAMC-supported medical liability reforms for the second time during the legislative year.

In the upcoming legislative year, medical liability reform will remain an AAMC priority. The AAMC will continue to press for reforms as a member of the Healthcare Coalition on Liability and Access (HCLA). Additional information about HCLA is available at: www.hcla.org. ***[Mitchell]***

Patient Safety Legislation

On July 22, the Senate passed patient safety provisions that establish a voluntary system and legal protections for reporting data in support of quality/patient safety improvement initiatives. The Senate-passed "Patient Safety and Quality Improvement Act of 2004," S. 720, is an amended version of the patient safety bill that was passed by the House (H.R. 663) on March 12, 2003.

The amended language confirms that existing patient access to medical records would not be pre-empted by the bill, which establishes legal protections for data that is reported for patient safety improvement purposes.

The House and Senate versions of the legislation will now need to be reconciled by a conference committee. Before leaving for the August recess, the Senate named its conferees, which include Senate Majority Leader Bill Frist (R-Tenn.) and Senators Edward Kennedy (D-Mass.), Judd Gregg (R-N.H.), Michael Enzi (R-Wyo.), Lamar Alexander (R-Tenn.), Christopher Dodd (D-Conn.), and John Edwards (D-N.C.). As of August 31, the House had not named its conferees. ***[Mitchell]***

Hospital Billings and Collections

On June 22 and 24, the House Ways and Means Subcommittee on Oversight and Investigation and the House Energy and Commerce Subcommittee on Oversight and Investigation held hearings on hospitals practices related to charges and billing.

The House Ways and Means Subcommittee focused on the tax-exempt status of hospitals and their hospital pricing practices, including whether the public receives a community benefit from not-for-profit hospitals consistent with the value of their tax-exempt status and the need for greater transparency of hospital prices. Witnesses included health care research experts, an employer health insurance purchaser, and representatives from the hospital community. It is expected that another hearing on the not for profit status of hospitals will be held in the Fall.

The House Energy and Commerce Subcommittee hearing focused on hospitals' billing and collection practices, examining whether the hospital community is uniformly adopting principles and guidelines issued earlier this year by the American Hospital Association

(AHA). Representatives from five large hospitals/health systems, consumer groups, and the Department of Health and Human Services testified. The departure of Subcommittee Chairman Jim Greenwood (R-Pa.) from Congress at the end of the year makes it unclear how the subcommittee will proceed on the subject.

Summaries of the hearings can be found at:
www.aamc.org/advocacy/library/washhigh/2004/062504/_2.htm and
www.aamc.org/advocacy/library/washhigh/2004/070204/_1.htm

The AAMC endorses the American Hospital Association's principles and guidelines to help hospitals better assist their patients. The AAMC encourages all hospitals to review their policies and practices, as well as those of their hired contractors, to ensure that billing and collection abuses are not occurring. ***[Davis Boyle]***

Health Information Technology Legislation

New legislation has been introduced in both chambers of Congress to provide guidance and resources for implementing health information technology through a combination of grants, loans, and payment incentives to promote adoption of information technologies. Senator Judd Gregg's (R-N.H.) "National Health Information Technology Adoption Act" (S. 2710) would help hospitals, physician groups, and other providers fund "Local Health Information Infrastructures" similar to the regionally linked systems in Indianapolis and Santa Barbara. Among the provisions in S. 2710 are new loan guarantees, as well as $50 million in annual matching grants (FY 2005 - FY 2010) for entities that "demonstrate financial need" and provide services to low income and underserved populations. Under the matching grants, the federal government would provide five dollars for every one dollar invested by the grant recipient.

In the House, Representative Patrick Kennedy's (D-R.I.) legislation, the "Josie King Act of 2004" (H.R. 4880), establishes nearly $3 billion in various grants for the development, implementation, and expansion of regional "health information exchanges." In some cases, the grants will be allocated according to provider participation rates in a particular state or region. Rep. Kennedy's bill also creates a "clearinghouse" of implementation strategies and best-practices, from which other providers can gain insight and information as they adopt health information technology. Additionally, H.R. 4880 mandates the certification and interoperability of health information technologies to help assure that providers invest in compatible infrastructures. H.R. 4880 would also direct health information exchanges to collect quality/patient safety data from participating providers. A portion of the data would be used to support a temporary six-year "pay-for-performance" project to evaluate whether quality-related incentives can influence provider behavior in a way that both enhances patient care and reduces Medicare costs. ***[Davis Boyle, Mitchell]***

Resident Hours Legislation

Senator Jon Corzine (D-N.J.), on April 30, 2003, and Representative John Conyers, Jr. (D-Mich.), on March 12, 2003, introduced similar legislation entitled the "Patient and Physician

Safety and Protection Act of 2003" (S. 952/H.R. 1228) which would make the regulation of resident work hours a Medicare hospital condition of participation.

S. 952/H.R. 1228 would establish specific limits on work hours, allow residents to file anonymous complaints regarding violations, and impose financial penalties for noncompliance. Specifically, the bill limits postgraduate trainees to 80 hours of work per week and 24 hours of work per shift. They must have at least 10 hours between scheduled shifts, at least one of every 7 days off, and at least one full weekend off per month. Emergency Department residents may work no more than 12 continuous hours within the Department. The bill also limits on-call responsibilities to no more than every third night.

The bills direct the Secretary of HHS to promulgate regulations regarding the supervision of residents and the transfer of patient care responsibilities from resident to resident. In addition, S. 952 specifies that the amount of time spent transferring patient care responsibilities from a resident to another individual cannot take more than 3 hours beyond the resident's 24 or 12-hour shift.

The bills also direct the Secretary to designate an individual within HHS to handle resident complaints. That individual would be authorized to conduct anonymous surveys of residents, conduct on-site investigations, and provide public disclosure of hospitals and programs in violation. The bill requires an annual report to Congress on the compliance of hospitals with such requirements.

The bills offer whistleblower protections to individuals who report violations to the Secretary, ACGME or hospital management and subject hospitals to penalties not to exceed $100,000 for violations in each resident training program in any 6-month period. In addition, S. 952 would allow a hospital to avoid such a fine if a corrective action plan is submitted to the Secretary of HHS.

S. 952 has 2 cosponsors, Sens. Jeff Bingaman (D-N.M.) and Frank Lautenberg (D-N.J.); H.R. 1228 has 7 cosponsors, Reps. Robert Andrews (D-N.J.), Donna M. Christensen (D-V.I.), Barney Frank (D-Mass.), Jim McDermott (D-Wash.), Nick Rahall (D-W.VA), Charles Rangel (D-N.Y.), and Pete Stark (D-Calif.) ***[Davis Boyle]***

Hospital Quality Reporting

The FY 2005 Medicare inpatient PPS final rule implemented the provision in the MMA to update the inpatient PPS standardized amount by the full market basket increase to those hospitals that submit data on 10 measures of quality care. According to the final rule, this increase is 3.3 percent. Hospitals that do not submit quality data will receive an update of market basket minus 0.4 percentage points, or 2.9 percent.

Linking the level of a hospital’s inpatient PPS payment with its submission of quality data is a new concept for the Medicare program. The ten quality indicators relate to Heart Attack (Acute Myocardial Infarction), Heart Failure and Pneumonia.

The program for the annual payment update is being referred to as the Reporting Hospital Quality Data for the Annual Payment Update (RHQDAPU). The procedures for participating in the RHQDAPU can be found on the net Exchange Web site at: **www.qnetexchange.org**. ***[Faerberg]***

Federal Funding of Emergency Health Services Furnished to Undocumented Aliens

On March 29, CMS held an Open Door Forum to solicit views about how to implement Section 1011 of the Medicare Modernization Act, which provides $250 million per year for fiscal years 2005-2008 for payments to eligible providers for emergency health services provided to undocumented aliens. Two-thirds of the funds are to be divided among all 50 states and the District of Columbia based on their relative percentages of undocumented aliens; one-third is to be divided among the six states with the largest number of undocumented alien apprehensions. Payments are made directly to hospitals, certain physicians, and ambulance providers. On July 21, the agency published a "proposed implementation approach" and requested that comments be submitted by August 16. At that time the agency also announced that it would hold a second Open Door Forum on August 2. The MMA requires that a process for providers to request payments from the funds be established by September 1. 2004.

The AAMC and others strongly opposed CMS's proposal to require providers to query patients directly about their immigration status, since this is likely to result in fewer undocumented aliens seeking treatment. The AAMC also objected to CMS's failure to use a rulemaking to implement this provision, and expressed concerns with other parts of the proposal. ***[Baer]***

Draft Supplemental Compliance Guidance for Hospitals

On June 8, the Office of Inspector General issued Draft Supplemental Compliance Program Guidance for Hospitals. The original compliance guidance for hospitals was issued in 1998. The draft guidance contains new compliance recommendations and an expanded discussion of risk areas.

In a comment letter, the AAMC noted that this and the previous compliance guidance are useful resources, but was concerned that several of the risk areas have been prematurely identified. In particular, billing for clinical trials should not become a risk area until CMS issues clarifications and makes efforts to educate providers. A second risk area, "billing Medicare or Medicaid substantially in excess of usual charges," should be not be identified as a risk area until CMS publishes a final rule. ***[Baer]***

Physician Self-Referral ("Stark") Regulation

On March 26, CMS published the long awaited second phase of the Physician Self-Referral Regulations. The rule prohibits a physician from referring Medicare and Medicaid patients for certain designated health services to entities with which the physician (or a member of the

physician's immediate family) has a financial relationship, unless an exception applies. The rule is effective July 26, 2004.

Phase II responds to comments submitted after the publication of the Phase I rules in January 2001, covers the remaining statutory exceptions, and creates several new regulatory exceptions for nonabusive financial relationships.

Phase I created an academic medical center exception. The AAMC submitted comments and requested changes in the exception. Among the changes adopted by this rule is the elimination of the requirement that an academic medical center include an accredited medical school. Assuming that other criteria are met, the exception will be available to hospitals or health systems that sponsor four or more approved medical education programs. In addition, the referring physician may be on the faculty of either the affiliated medical school or the accredited academic hospital.

In an FAQ published on the CMS website, the Agency stated that "all recruiting arrangements must comply with the new regulations as of July 26, 2004." One of the prohibitions in the Stark regulation that hospitals may not impose a non-compete requirement on physicians. All contracts with physicians should be reviewed to ensure compliance with this, and other provisions in the final regulations. ***[Baer]***

IRS Proposed Regulation on FICA Student Exception

On February 25 the IRS published a proposed rule and notice of a public hearing on the issue of the applicability of the student FICA exception to medical residents. To qualify for the student exception, an individual must be employed by a school, college, or university and have student status. The IRS contends that a hospital cannot qualify as a school, college, or university. An individual would not have student status if any of the following criteria are met: (1) working more than 40 hours per week; (2) performing services requiring knowledge of an advanced type in a field of science or learning; (3) being eligible for vacation, sick leave, paid holidays, and participation in a retirement plan; and (4) requiring licensure by a government entity in order to perform certain functions.

If finalized, the rule would apply to services performed on or after the date of publication. The IRS is silent as to how services performed prior to that date will be treated.

On June 16, 2004, the IRS held a public hearing on the proposed rule. Dr. William L. Thomas, Executive Vice President for Medical Affairs, MedSTAR Health, testified on behalf of the AAMC. In his testimony, Dr. Thomas urged the IRS "to withdraw the proposed rule that would deny medical residents the ability to use the FICA student exception."

The notice and information about the hearing are available at:
www.access.gpo.gov/su_docs/fedreg/a040225c.html. ***[Baer]***

Medicare Payment Advisory Commission (MedPAC)

In June, MedPAC released two reports of interest. The Data Book contains data charts and graphs on a variety of topics, includiog national health care and Medicare spending, the Medicare beneficiary demographics, and information about various provider groups. Of note, is the chart on hospitals total margins, which shows that the total margin for major teaching hospitals declined from 1.9 percent in 2000 to 1.1 percent in 2001.

MedPAC's June 2004 *Report to the Congress: New Approaches in Medicare* fulfills MedPAC's legislative mandate to examine issues affecting the Medicare program, including the implications of changes in health care delivery for the Medicare program.

Issues addressed in the report include:

- implementing the new drug benefit and the new chronic care management; program mandated under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003;
- Beneficiaries who are dually eligible for Medicare and Medicaid;
- Potential improvements to purchasing and paying for services under the traditional fee-for-service Medicare program; and
- Diffusion of health care information technology.

Both reports are available on MedPAC's web site: **www.medpac.gov** ***[Fisher]***

Practicing Physician's Advisory Council

AAMC constituents and staff will attend the quarterly meeting of the Practicing Physicians' Advisory Council (PPAC) meeting on August 30. PPAC's purpose is to provide input to CMS on issues of importance to the physician community. Topics to be covered during the August 30 meeting include: the Physician Fee Schedule, Evaluation and Management (E & M) Documentation Guidelines, Medical Economics Index and Proxy Indicators, 2005 Medicare Modernization Act issues and activities, Average Sales Price, and Physician Regulatory Issues Team, Enrollment and Pecos, Chronic Care Improvement Program and Efforts to Improve the Accuracy of Call Center Information. ***[Dodero]***

Stem Cell Research

Efforts continue to expand President Bush's August 9, 2001, limitation on the number of human embryonic stem cell lines available to federally funded researchers. Legislation to lift the Bush-imposed limitation (H. R. 4682) was introduced by Representatives Michael Castle (R-Del.) and Diana DeGette (D-Colo.) on June 24 and currently has over 150 co-sponsors. The AAMC has endorsed H.R. 4682. However, no legislation on stem cell research is likely to be considered before the end of the session.

The AAMC joined with 141 national patient groups, universities, and scientific societies in a June 23 letter calling on President Bush to expand the Administration's policy for federal

funding of embryonic stem cell research. The letter, which was initiated by the Coalition for the Advancement of Medical Research (CAMR), was released at a press conference on Capitol Hill. The letter is available on the CAMR Web site at: **www.camradvocacy.org/fastaction/Change6-17-20041.pdf**

Under the President's policy, only human embryonic stem cell lines created before August 9, 2001 are eligible for funding. The President initially said that his decision would permit federal funding for research on "more than 60" stem cell lines. However, at the end of August, only 22 stem cell lines are available to federally funded researchers. According to a Boston Globe survey published on May 23, 128 additional stem cell lines have been created since August 9, 2001. The paper reports that of those cell lines, 94 were created abroad and 34 were created in the United States and that 54 of these new lines currently are available to non-federal researchers.

A bipartisan coalition of more than 200 Members of the House of Representatives sent a letter April 28 urging President Bush to "expand the current policy concerning embryonic stem cell research." The letter, organized by Representatives Castle, DeGette, Randy "Duke" Cunningham (R-Calif.), and Calvin Dooley (D-Calif.), notes "it is increasingly difficult to attract new scientists to this area of research because of concerns that funding restrictions will keep this research from being successful." In a press statement, AAMC President Jordan J. Cohen, M.D., declared, "This strong showing of bipartisan support is gratifying and a clear indication that Congress realizes how important these research tools are to medical research." A similar Senate letter, organized by Senators Arlen Specter (R-Pa.) and Tom Harkin (D-Iowa), was sent to the president on June 3 with 58 signatures.
[Mazzaschi, Moore]

NIH Conflicts of Interest

NIH Director Elias Zerhouni, M.D., outlined a series of aggressive proposals to strengthen the ethics system at NIH in response to concerns about consulting agreements between agency employees and industry. He announced his proposals on June 22 at the third in a series of hearings on this issue before the House Energy and Commerce Subcommittee on Oversight and Investigations. Chairman James Greenwood (R-Pa.) and other members of the subcommittee generally praised the new initiatives while reserving final judgment until learning more about the implementation of the proposals. Dr. Zerhouni's testimony is available at: **www.nih.gov/about/director/062204zerhouni_COI.pdf**.

Dr. Zerhouni described three core elements of reforming the ethics process at NIH: applying review of applications for outside activities by scientific peers; requiring full disclosure and transparency in the program; and working to reduce, restrict, or eliminate the types of activities about which the subcommittee has raised concerns. He announced that NIH will prohibit employees from:

- Holding of stock in individual biotechnology and pharmaceutical companies, as is done at the Food and Drug Administration;

- Accepting any award unless the award has been pre-screened by an independent advisory committee of non-government individuals, and a determination is made that the award meets the regulatory definition of bona fide;

- Holding membership on corporate boards of the pharmaceutical and biotechnology industries; and

- Consulting (including speaking) with NIH grantee institutions for compensation or any other form of personal remuneration. NIH will continue to encourage consultation with grantee institutions as part of official duties. In addition, NIH senior leadership will be prohibited from consulting (including speaking) with non-profits that are not grantee institutions.

Senior employees, as well as all employees involved in extramural funding decisions, would be prohibited from consulting with industry for compensation or any other form of remuneration. Other employees would be permitted to consult only if the arrangement has been reviewed by the NEAC and approved by the DEC, and 1) payment may not include stock or stock options; 2) annual compensation from all outside activities with industry must be limited, and no more than half of that limit may come from any one source; and 3) the number of hours annually that an employee can spend on all outside activities with industry is capped at 400 hours;

To continue to be able to recruit and retain the best scientific expertise while expediting translation of research advances, Dr. Zerhouni said he "will encourage NIH scientists to continue teaching, speaking or writing about their research as part of their official duties." To encourage scientific interactions involving the exchange of knowledge and the exercise of intellectual leadership by NIH scientists, NIH will continue to allow certain types of outside activities - including teaching and lecturing opportunities and collaborations with the private sector - but only under clear, rigorous rules meant to eliminate conflicts of interest. ***[Moore, Fishburn]***

NIH and Open Access Publishing

The draft House Appropriations Committee's report on the FY 2005 Labor-HHS-Education Appropriations Bill contain language recommending that the NIH develop a policy requiring that "a complete electronic copy of any manuscript reporting work supported by NIH grants or contracts" be provided to NIH's PubMed Central "upon acceptance of the manuscript for publication in any scientific journal…" The report also called for NLM to make "these reports, together with supplemental materials, freely and continuously available no later than six months after publication, or immediately in cases in which some or all of the publication costs are paid with NIH grant funds. For this purpose, 'publication costs' would include fees charged by a publisher, such as color and page charges, or fees for digital distribution." The Senate Appropriations Committee has yet to address this issue.

Subsequently, NIH Director Elias Zerhouni, M.D., held a meeting on July 28 with invited editors and publishers to discuss NIH's evolving policy on open access publishing. Dr.

Zerhouni said that NIH has been considering the open access issue for some time, and although the House Appropriations Committee's report language is accelerating discussions, he is ready to issue a new, draft NIH policy on publishing for comment. Dr. Zerhouni said that "the status quo is unacceptable" for two reasons: 1) there is a growing demand by the public for access to research results they fund, and technology has made it possible to meet this demand; and, 2) NIH staff need access to published research results in order to fulfill their accountability and productivity assessment needs. Dr. Zerhouni said that NIH would issue a revised draft publication policy that will be open for public comment. It has not yet been published. ***[Mazzaschi]***

Proposed Rule on Research Misconduct

On June 15, the AAMC, along with the Association of American Universities (AAU), the Council on Governmental Relations (COGR), and the National Association of State Universities and Land-Grant Colleges (NASULGC), sent a comment letter to Office of Research Integrity (ORI) Director Chris Pascal on the proposed revisions to the Public Health Service Policies on Research Misconduct, issued April 15. In the letter, the four organizations strongly endorse the proposed changes to the definition of "research misconduct" and the incorporation of standard elements that must be present in order to determine that research misconduct has occurred. "These key components provide the critical foundation for a common and systematic approach to addressing allegations of research misconduct, and bring the proposed regulations into conformity with the Federal Policy on Research Misconduct issued by the Office of Science and Technology Policy (OSTP)." However, the groups indicate two principal problems with the regulations as proposed: a question of scope or applicability and the evidentiary standards related to the burden of proof. The letter outlines additional concerns of the four groups related to confidentiality, coordination with other agencies, the definitions of allegation and research record, general responsibilities for compliance, institutional investigations, completing the research misconduct process, and ORI allegation assessment. The letter is available at: **www.aamc.org/advocacy/library/research/corres/2004/061504.pdf** ***[Ehringhaus]***

Proposed Rule for IRB Registration

The HHS Office for Human Research Protections (OHRP) issued a notice of proposed rulemaking (NPRM) in the July 6 *Federal Register* (69 FR 40584) proposing to require registration of institutional review boards (IRBs) that review human subjects research conducted or supported by HHS and that are designated under an assurance of compliance approved for federal wide use by OHRP. Comments on the proposed rule are due by October 4, 2004.

The proposal grows out of the 1998 Office of the Inspector General recommendation that IRBs should register with the federal government on a regular basis as part of an effort to develop a more coordinated means of assessing IRB performance and enhancing the government's ability to identify emerging problems. The new proposal is an expansion of the registration process put in place in December 2000, which required certain information to be included in an assurance of compliance filed with OHRP and requested other information on a voluntary basis. The proposal seeks to require submission of most of the information listed

on the current IRB registration form. The Food and Drug Administration (FDA) is simultaneously proposing substantially similar requirements, and OHRP and FDA intend to operate a single registration system for HHS in which all IRBs that review human subjects research conducted or supported by HHS or clinical investigators regulated by the FDA can be registered. Though only the name and location of registered IRBs and registration numbers would be posted on the registration Web site, other information collected during the registration process would be subject to the Freedom of Information Act (FOIA), and unless protected under that act, would be available to the public upon request.

Information proposed to be required includes name, earned degree, title, specialty, affiliation, gender, telephone, fax, email, and mailing address of the senior or head official who is responsible for overseeing the IRBs, similar information on the IRB chair, and IRB roster that includes similar information about IRB members (except contact information), the approximate number of active protocols undergoing initial and continuing review, the approximate number of active protocols supported by HHS (by broad ranges), the approximate number of full time positions devoted to the IRBs administrative activities, an indication of whether or not the institution is accredited by a human subjects accrediting organization and the name of the organization (to help OHRP evaluate the extent and value or IRB accreditation). OHRP is not proposing to collect information about IRB review of research supported by agencies other than HHS. ***[Ehringhaus]***

Faculty Effort Reporting

Several high profile compliance cases have focused the university community's attention on issues related to the estimation and reconciliation of faculty effort in the proposing and management of research grants. Two major areas of interpretation and policy have been subject to controversy: 1) the treatment of clinical practice compensation that is paid by a separately organized practice plan, and 2) the treatment of faculty effort under the provisions of K (Career Development) Awards issued by the NIH.

NIH's current guidelines for awards (other than K awards) require that the only salary that can be included in institutional base salary is salary that: 1) is guaranteed by the university, 2) is shown on the university appointment form and paid by the university, and 3) is included and accounted for in the university's effort report. For universities with separately organized faculty practice plans, the NIH guidelines often mean that the faculty members' clinical salary and effort must be excluded from calculations of their salary and effort for university effort reporting purposes. AAMC has proposed a modification to the NIH's policy on such effort to allow additional flexibility on whether such effort may be included. The AAMC proposal is under review by NIH and the Department of Health and Human Services.

For K (Career Development) Awards, NIH has recently conformed the calculation of effort to that for other NIH awards, thus reducing for institutions one area of confusion in complying with applicable effort reporting guidelines. ***[Ehringhaus, Mazzaschi]***

Revised OMB Agency Peer Review Guidelines

The Office of Management and Budget (OMB) issued April 15 revised standards for peer review of scientific information disseminated by or on behalf of federal agencies. In particular, OMB established requirements for an additional level of peer review for an agency's dissemination of highly "influential" information, such as information supporting a major regulation or otherwise having a significant economic impact on society. In a joint letter co-signed by the Federation of American Societies for Experimental Biology (FASEB), the AAMC objected to OMB's first bulletin, proposed in September 2003, as being inappropriately restrictive and potentially interfering with timely decision making by the Public Health Service. The revised bulletin considerably improves upon the earlier version, and provides far more flexibility and deference to scientific and public health prerogatives of government agencies. For example, the original version set forward criteria for peer selection that would have precluded the use of agency grantees in an OMB-mandated peer review, under the presumption that receipt of a research grant could constitute a conflict of interest in critiquing a funding agency's dissemination of information. The revised bulletin does not consider agency grantees to hold such conflicts. The revised bulletin further provides various exemptions from the added peer review requirement, such as in the case of urgent findings from a clinical trial, where the trial itself has already been peer reviewed, largely addressing a major concern of the AAMC.

The AAMC and FASEB commended the OMB's revisions in a second comment letter on May 28, noting that OMB had been especially attentive to the views and concerns of the scientific community. However, both organizations remain wary of how successfully the requirements can be implemented. ***[Heinig]***

First Responder Legislation

Following a number of hearings, the "Faster and Smarter Funding for First Responders Act of 2004" (H.R. 3266), was amended and approved by the House committees on Energy and Commerce, Transportation and Judiciary and placed on the House calendar on June 21. The revised bill is a compromise drawn up by the committees following controversy over the funding formula for Department of Homeland Security (DHS) funds. The bill is designed to alleviate administrative bottlenecks in the states that have prevented first responders from receiving preparedness funds administered by the DHS. It also revises the funding formula so grants are awarded to states and regions based on threat level, rather than population. There has been no action in the Senate. ***[Froyd]***

Project BioShield

The President signed the Project Bioshield Act (PL 108-276) into law on July 21, following final approval by the House on July 14. The legislation authorizes funds to encourage pharmaceutical and biotechnology companies to develop bioterrorism countermeasures. First proposed in the 2003 State of the Union address, Project Bioshield provides $5.6 billion over ten years. The final bill guarantees this funding cannot be diverted for other purposes, but

Congress retains discretion over the program's annual appropriations, such as the $890 million approved for FY 2004.

Senators Judd Gregg (R-N.H.), Joe Lieberman (D-Conn.) and Orrin Hatch (R-Utah) are said to be working on "Bioshield II," a bill that will provide liability protections for firms creating vaccines or drugs that could cause injuries. ***[Froyd]***

Health Disparities Legislation

The AAMC sent letters to Senate Majority Leader Bill Frist (R-Tenn.), Senate Minority Leader Tom Daschle (D-S.D.) and Rep. Elijah Cummings (D-Md.) on May 24 endorsing their bills addressing health disparities. The letters are available on the Web at: **www.aamc.org/advocacy/library/start.htm**. No action has been taken on any of these bills.

Sen. Frist introduced the "Closing the Health Care Gap Act of 2004" (S. 2091) on February 12 with 8 cosponsors. It includes provisions to improve health care quality through standardized data collection and analysis; expand access to health care to disparity populations through grants to hospitals, health centers and other health entities; improve national leadership by formally authorizing an HHS Office of Minority Health; enhance education and training of disparity populations by reauthorizing the Title VII diversity training programs; and expand research at AHRQ and NIH to close the disparities gap. On March 12, Sen. Frist reintroduced the bill as S. 2217, which is identical to the original with the addition of a new section designed to enhance access through health insurance tax credits.

Sen. Daschle and Rep. Cummings introduced the "Healthcare Equality and Accountability Act" (S. 1833 and H.R. 3459), on November 6, 2003. The bill includes provisions addressing a range of diseases and conditions. In addition, it includes a section on improving culturally and linguistically appropriate health care through outreach programs, research grants and a GAO report. The workforce diversity section calls for a report, a national working group, technical clearinghouse, data collection, grants to institutions, career support, as well as research and training focused on improving diversity. Similar to the Frist bill, it reauthorizes the Health Careers Opportunity Program (HCOP) under Title VII and formally authorizes an Office of Minority Health within HHS, as well as in CMS and the FDA. S. 1833 has 21 cosponsors, while H.R. 3459 has 90 cosponsors. ***[Froyd]***